

EXHIBIT 3

Vladeck, Ph.D., Bruce C.
New York, NY

May 4, 2007

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

-----X MDL NO. 1456
IN RE: PHARMACEUTICAL INDUSTRY : CIVIL ACTION:
AVERAGE WHOLESALE PRICE LITIGATION : 01-CV-12257-PBS

-----X
THIS DOCUMENT RELATES TO: :
U.S. ex rel. Ven-A-Care of the : CIVIL ACTION:
Florida Keys, Inc. v. Abbott : 06-CV-11337-PBS
Laboratories, Inc. :
-----X

IN THE CIRCUIT COURT OF
MONTGOMERY COUNTY, ALABAMA

-----X
STATE OF ALABAMA, : CASE NO.
Plaintiff, : CV-05-219
v. :
ABBOTT LABORATORIES, INC., : JUDGE
et al., : CHARLES PRICE
Defendants. :
-----X

Henderson Legal Services
202-220-4158

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1 probably other members of the staff of the office
2 administrator probably would have been involved,
3 as would additional staff in the Office of
4 Legislation and Policy, in addition to the
5 individuals I named earlier.

6 Q. And it involved numerous meetings at
7 which the -- the -- the possibilities were
8 discussed; I take it?

9 MS. BROOKER: Objection. Form.

10 A. I would say we were, in 1996 and 1997 -
11 - certainly probably beginning in 1995, there
12 were very frequent conversations about budgetary
13 issues and policies with potential budgetary
14 impacts of one kind or another, and there was
15 always a list of potential policies and changes
16 to Part B drug reimbursement was frequently on
17 those lists, and was not discussed at every
18 meeting, but was frequently discussed.

19 Q. How many alternatives were discussed?

20 MS. BROOKER: Objection. You should
21 not discuss exactly what -- you should not
22 discuss any of your deliberations, so you

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1 shouldn't talk about -- I mean, that's -- that's
2 prohibited.

3 MR. COOK: Well, are you instructing
4 him not to answer?

5 MS. BROOKER: You can talk about what
6 official policy was.

7 MR. COOK: All right. I'll make it
8 easy.

9 Q. In your internal deliberations at HCFA,
10 how many alternative methods of reimbursement did
11 you consider?

12 A. I couldn't say. I -- it's not a
13 question of privilege. I couldn't say.

14 Q. Okay. But within your internal
15 deliberations, you did consider alternative
16 methods of reimbursement. Correct?

17 A. That is correct.

18 Q. And, again, to -- to make the record as
19 sharp as possible, what did you discuss in those
20 deliberations?

21 MS. BROOKER: Objection. You cannot
22 discuss exactly what your deliberations were.

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1 And I also object that these questions
2 are incredibly vague. So, I object to form. I
3 don't know exactly what program we're even
4 talking about. I don't know what time period
5 we're talking about. I don't know what the
6 specifics are that you're talking about in this
7 whole line of questions.

8 MR. COOK: But you understand enough
9 that you won't let him answer it?

10 MS. BROOKER: If he's going to talk
11 about internal deliberations. And -- and, again,
12 just for the record, it's not that I won't let
13 him talk about it. I am here to protect on --
14 not on behalf of the witness, but on behalf of
15 the government, deliberative process privilege.
16 It's not my privilege. It's not the witness'
17 privilege. It's the federal government's
18 privilege.

19 MR. COOK: All right. The United
20 States, who has sued my client, will not allow
21 the witness to talk about it.

22 Is that fair to say?

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1 MS. BROOKER: I don't think that's a
2 fair characterization.

3 MR. COOK: Okay.

4 MS. BROOKER: Look, Chris --

5 MR. COOK: I know. I know.

6 MS. BROOKER: We have this issue before
7 the Judge. There's no reason to bicker about it
8 before the witness. Let's just all be
9 professional about it.

10 Q. And so, it is fair to say that during
11 the time you were the administrator of HCFA, the
12 agency did not choose to change the manner in
13 which it reimbursed Medicare Part B drugs?

14 MS. BROOKER: Objection. Form.

15 A. I would -- I would frankly personally
16 object to that characterization because I had a
17 growing feeling -- again, I would put this in a
18 period probably beginning about 1995 through the
19 time I left the government -- of frustration that
20 we were significantly overpaying for Part B
21 drugs, and that because of some combination,
22 frankly, of political and legal constraints, we

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<p style="text-align: right;">Page 190</p> <p>1 were unable to change it.</p> <p>2 Again, whether that was a matter of law</p> <p>3 or a matter of political judgment, whether I was</p> <p>4 clear then, I'm not clear now, but it was</p> <p>5 certainly a source of very great frustration to</p> <p>6 me that we continued to pay what I believed was</p> <p>7 excessive amounts for the drugs.</p> <p>8 Q. And so, "choose" was a bad choice of</p> <p>9 words?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. Did not, in fact, change the way</p> <p>12 in which it reimbursed it, for several reasons?</p> <p>13 MS. BROOKER: Objection. Form.</p> <p>14 A. Those methods were not, in fact,</p> <p>15 changed until 2004, I believe.</p> <p>16 Q. You indicated that political</p> <p>17 considerations were one of the bases -- let me</p> <p>18 rephrase that.</p> <p>19 You indicated the political pressures</p> <p>20 were one of the reasons why the methodology was</p> <p>21 not changed. Correct?</p> <p>22 A. I did, yes. That's correct.</p>	<p style="text-align: right;">Page 192</p> <p>1 negatives in it. I'm not even going to try to</p> <p>2 clean that one up. I apologize.</p> <p>3 You had communications with Congress</p> <p>4 during this time period about the issue of</p> <p>5 Medicare Part B reimbursement for prescription</p> <p>6 drugs?</p> <p>7 A. I don't know the extent to which I did</p> <p>8 personally, but certainly at the staff level</p> <p>9 there was continual conversation about this</p> <p>10 issue.</p> <p>11 Q. Do you know the extent to which the</p> <p>12 facts underlying these policy decisions were</p> <p>13 communicated by your staff to Congress?</p> <p>14 MS. BROOKER: Objection. Form.</p> <p>15 A. I don't know the extent to which I am a</p> <p>16 reliable source of information in this regard,</p> <p>17 but it is my perception, again, that the general</p> <p>18 sense of a 15, 20 percent spread between average</p> <p>19 wholesale price and actual acquisition or actual</p> <p>20 market cost was very widespread within the policy</p> <p>21 community in Washington, so that the</p> <p>22 Congressional staff and the HCFA staff and other</p>
<p style="text-align: right;">Page 191</p> <p>1 Q. And it's possible that legislative</p> <p>2 impediments were one of the reasons why the</p> <p>3 methodology was not changed. Correct?</p> <p>4 MS. BROOKER: Objection. Form.</p> <p>5 A. Again, I would -- I would restate it.</p> <p>6 What I was trying to say was that we believed</p> <p>7 that -- there's sort of two parts to this -- that</p> <p>8 any effort to change it through any mechanism</p> <p>9 would create political objections and might well</p> <p>10 prevent us from moving forward. Some of those</p> <p>11 barriers might have been legislative, but whether</p> <p>12 we actually required legislation to make changes,</p> <p>13 again, is something I'm a little bit unclear</p> <p>14 about.</p> <p>15 Q. It is fair to say that one of -- it was</p> <p>16 not a reason for the lack of a change in</p> <p>17 methodology that you were relying upon average</p> <p>18 wholesale price to represent an average of</p> <p>19 acquisition prices?</p> <p>20 MS. BROOKER: Objection. Form.</p> <p>21 A. Please restate that.</p> <p>22 Q. You're right. That has way too many</p>	<p style="text-align: right;">Page 193</p> <p>1 HHF staff and, frankly, industry representatives,</p> <p>2 would have all seen the same documents, would all</p> <p>3 have shared the same sort of gossip and</p> <p>4 perceptions.</p> <p>5 In addition to which certainly at the</p> <p>6 time of the President's speech, I'm almost</p> <p>7 certain in 1996, and it's possible in 1995 there</p> <p>8 were official savings estimates from OMB and the</p> <p>9 Congressional budget office of what an adoption</p> <p>10 of, say, a proposal to go to 85 percent of AWP</p> <p>11 would save the Medicare program.</p> <p>12 So, there were numbers, quantitative</p> <p>13 estimates, of the effect of this change that were</p> <p>14 blessed by the official numbers blessers, so</p> <p>15 there was sort of a common set of parlance</p> <p>16 expectation and understanding about the magnitude</p> <p>17 of these issues.</p> <p>18 Q. And from -- you mentioned political</p> <p>19 pressures that -- that prevented changes, and a</p> <p>20 change to methodology.</p> <p>21 From where did those political</p> <p>22 pressures come, in your experience?</p>

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June 21, 2007

<p style="text-align: right;">Page 538</p> <p>1 Correct?</p> <p>2 MS. BROOKER: Objection, and asked</p> <p>3 and answered.</p> <p>4 A. Possibly, but it would have been of</p> <p>5 no relevance.</p> <p>6 Q. Well, again, if anybody were to</p> <p>7 suggest that HCFA had no way of knowing in 1996</p> <p>8 that for generic drugs the spreads could be 60 to</p> <p>9 85 percent below the average published wholesale</p> <p>10 price, that would not be correct.</p> <p>11 Isn't that true?</p> <p>12 MS. BROOKER: Objection.</p> <p>13 A. But that information was irrelevant</p> <p>14 to Medicare payment policy.</p> <p>15 Q. And why was it irrelevant?</p> <p>16 A. Because Medicare was required by</p> <p>17 law to pay the average wholesale price.</p> <p>18 Q. Well, in 1996, the -- there was no</p> <p>19 statute adopting AWP; it was a Medicare</p> <p>20 regulation. Correct?</p> <p>21 A. No, I believe that regulation was</p> <p>22 consistent with OBRA '90, which allowed one of</p>	<p style="text-align: right;">Page 540</p> <p>1 A. That's correct.</p> <p>2 Q. And Congress rejected that proposal</p> <p>3 in favor of 95 percent of AWP.</p> <p>4 A. That's correct.</p> <p>5 Q. And do you know whether Congress</p> <p>6 knew that the spreads between transaction prices</p> <p>7 and AWPs could be as much as 1,000 percent?</p> <p>8 MS. BROOKER: Objection.</p> <p>9 A. I would never presume to suggest</p> <p>10 what Congress knew of anything.</p> <p>11 MR. EDWARDS: What I want to do is</p> <p>12 mark BMS Exhibit - Exhibit BMS 004? This will now</p> <p>13 be Exhibit BMS 003, as I decided not to mark the</p> <p>14 Barron's article.</p> <p>15 So, this is Exhibit BMS 003, and</p> <p>16 it's an excerpt from a report of the Committee on</p> <p>17 the Budget of the House of Representatives dated</p> <p>18 June 24, 1997.</p> <p>19 THE VIDEOGRAPHER: The time is 3:09</p> <p>20 p.m. We're going off the record, Concluding Tape</p> <p>21 No. 9.</p> <p>22 (Recess taken.)</p>
<p style="text-align: right;">Page 539</p> <p>1 three choices, two of which had been precluded by</p> <p>2 the Office of Management and Budget in its refusal</p> <p>3 to permit HCFA to conduct the survey of average</p> <p>4 acquisition costs.</p> <p>5 THE VIDEOGRAPHER: We have</p> <p>6 approximately five minutes left on this tape.</p> <p>7 Q. Well, in any event, the information</p> <p>8 that transaction prices for generic drugs could be</p> <p>9 60 to 85 percent below the average published</p> <p>10 wholesale price was out there and available to</p> <p>11 anybody who read this Barron's article. Correct?</p> <p>12 MS. BROOKER: Objection.</p> <p>13 A. Apparently, yes.</p> <p>14 Q. Now, you talked a little bit about</p> <p>15 the Balanced Budget Act of 1997 in your earlier</p> <p>16 testimony. Do you recall that?</p> <p>17 A. Yes.</p> <p>18 Q. And leading up to the Balanced</p> <p>19 Budget Act, the administration made a proposal</p> <p>20 that reimbursement be based on actual acquisition</p> <p>21 cost. Correct?</p> <p>22 MS. BROOKER: Objection.</p>	<p style="text-align: right;">Page 541</p> <p>1 (Exhibit BMS 003 marked for</p> <p>2 identification.)</p> <p>3 THE VIDEOGRAPHER: The time is 3:22</p> <p>4 p.m. We're going back on the record, starting</p> <p>5 Tape No. 10.</p> <p>6 Q. Dr. Vladeck I want to hand you what</p> <p>7 we have marked as Exhibit BMS 003, which I stated</p> <p>8 earlier is an excerpt from a report of the</p> <p>9 Committee on the Budget of the House in connection</p> <p>10 with the Balanced Budget Act of 1997. The report</p> <p>11 is dated June 24th, 1997.</p> <p>12 Do you have that in front of you?</p> <p>13 A. I do.</p> <p>14 Q. Okay. I want to direct your</p> <p>15 attention to the second page of this document, the</p> <p>16 middle of the page. You'll see it says Section 10</p> <p>17 616, "Reimbursement for Drugs and Biologicals"?</p> <p>18 A. Yes.</p> <p>19 Q. And it says -- it describes the</p> <p>20 current law and explains the proposed change, and</p> <p>21 then under "reason for change" it says:</p> <p>22 "The Inspector General for the</p>

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